

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

MDL NO. 2804

Case No. 17-MD-2804

THIS DOCUMENT RELATES TO:

Judge Dan Aaron Polster

Salmons v. Purdue Pharma L.P., et al.
MDL Case #1:18-OP-45268

Flanagan v. Purdue Pharma L.P., et al.
MDL Case #1:18-OP-45405

Doyle v. Purdue Pharma L.P., et al.
MDL Case No. #1:18-op-46327

Artz v. Purdue Pharma, L.P., et al.
MDL Case No. #1:19-op-45459

**PLAINTIFFS' REPLY IN SUPPORT OF THEIR CONSOLIDATED
MOTION FOR CLASS CERTIFICATION**

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MEMORANDUM IN SUPPORT

Come now Melissa Barnwell, Ashley Poe, Jacqueline Ramirez, and Roman Ramirez and file this Reply Brief in further support of their Consolidated Motion for Class Certification:

I. INTRODUCTION

The Named Plaintiffs ask the Court to certify a nationwide class of guardians who seek injunctive relief for monitoring and surveillance for children in their care who were born with Neonatal Abstinence Syndrome (NAS).¹ When combined with an abatement recently agreed to in the Purdue bankruptcy global settlement,² the relief sought here will alleviate the Guardians' care burden. To be clear, the relief sought is *not* a cash payment for personal injuries suffered by the NAS children. Guardians seek injunctive relief designed by medical experts to relieve guardians from the twin burdens of determining what specialized monitoring and surveillance care their wards need and how to provide for it for them.

There is hope for these children, because “most of [their] problems can be ameliorated if prevented or detected early.” Dr. Kanwaljeet Anand, Professor of Pediatrics and Anesthesiology at Stanford University Medical Center, Anand Depo. Excerpts, Ex. 2, of Bilek Dec., at 228:6-8. But without a class action certified, the opportunity will be lost. This motion affords the Court a meaningful opportunity—perhaps the only such opportunity to arise in this MDL—to help the most innocent victims of Defendants' conspiracy to flood the U.S. with opioids.

This Court can create a class by any of several means. Under Fed. R. Civ. P. 23(b)(2), it can certify single-state classes for guardians who reside in California or Ohio, and it can certify a

¹ Also known as Neonatal Opioid Withdrawal Syndrome (NOWS). Children with NAS/NOWS are at significant increased risk of adverse neurodevelopmental consequences, impaired executive functions, and adverse neuropsychiatric outcomes. Anand Report at Bilek Dec., Ex. 5 to Consolidated Motion for Class Certification, at 6-7.

²See Bilek Declaration (“Dec.”), Ex. 10 and 11.

nationwide class under RICO. The Court can also certify the same classes under Rule 23(b)(3) or by employing Rules 23(b)(3) and 23(c)(4) together and creating a class limited to identified issues.³

This Reply addresses the objections to certification that are raised in *Defendants’ Opposition to NAS Plaintiffs Motion for Class Certification*, Doc. # 3522 and Doc. # 3523 (“Oppositions” or “Opp.”). Section II shows that the Named Plaintiffs satisfy the Rule 23(a) requirements that apply to all options for certifying a class. Section III rebuts Defendants’ criticisms of the proposed class definition. Section IV establishes that the Defendants acted on grounds generally applicable to all class members by conspiring to maximize the volume of opioids prescribed, distributed, and consumed in the U.S.; that common evidence of their conspiracy can be used to establish liability to all class members; and that, consequently, the requirements for certifying both single-state class actions and a nationwide RICO class action under Rule 23(b)(2) are met. Section V shows that Rule 23(b)(3) certification is also proper by rebutting Defendants’ predominance and superiority arguments. Finally, Section VI shows that the Court has discretion to certify a limited issues class.

II. THE NAMED PLAINTIFFS SATISFY THE REQUIREMENTS OF RULE 23(A)⁴

A. The Named Plaintiffs are Typical Members of the Class

The class definition requires (1) guardianship over (2) a child diagnosed with NAS (3) whose birth mother had a prescription for opioids prior to that birth, or alternatively and more

³ The Sixth Circuit approved the latter approach in *Martin v. Behr Dayton Thermal Prod. LLC*, 896 F.3d 405 (6th Cir. 2018), *cert. denied*, 139 S.Ct. 1319 (2019). It also cited *Martin* with approval when reviewing the Court’s certification of a negotiation class. *In re Nat’l Prescription Opiate Litig.*, 976 F.3d 664, 675 (6th Cir. 2020).

⁴ The request by Michelle Frost, an Ohio grandmother of minor child M.F., to be appointed class representative is withdrawn. Representation of the Ohio class was assumed by Ashley Poe, who was granted leave by this Court to intervene in the Ohio class action and apply for class representative in February 2020, (Motion to Intervene, Case 1:18-op-46327-DAP, Doc. # 32 (02/24/20) and Order Case 1:18-op-46327-DAP, Doc. # 40 (04/03/20)). Defendants do not contest that Ms. Poe has completed all requested class representative discovery and appeared for deposition. Opposition, *passim*.

narrowly, (4) a prescription during pregnancy. Consolidated Motion, *passim*. All class representatives meet all elements and are typical members of the class they seek to represent.

To make it seem as though the Named Plaintiffs are not typical, Defendants improperly graft an additional requirement onto the class definition and make the new definition the centerpiece of their Opposition. They replace (2)—a child diagnosed with NAS—with a child diagnosed with “opioid-related” NAS. Opp. at 21. Then they argue that the Named Plaintiffs are not typical because the children at issue did not receive Defendants’ newly invented “Diagnosis”. Defendants are not at liberty to change the class definition. The Named Plaintiffs are typical because all are guardians for children who meet condition (2): a diagnosis of NAS at birth.

The purpose of the typicality requirement is to establish that a named plaintiff is a suitable representative for the group of people who will be bound by a judgment. Defendants repeatedly sow confusion about this straightforward matter by arguing that, to establish typicality, the Named Plaintiffs must show that the class will win. For example, they contend that the Named Plaintiffs cannot be typical because injunctive relief is not available under RICO. Opp. at 29. A certified class may lose at trial even if a named plaintiff is typical.

The remaining grounds on which the Defendants contest typicality all argue that individualized proof of exposure, injury, causation, and other matters are required. Opp. at 24-26. These objections, all of which attempt to sneak a predominance requirement into the typicality requirement, are addressed below.

B. The Class Complaint Raises Common Issues⁵

⁵ Defendants note the Court forbade parties from citing the Negotiation Class memorandum opinion. Opp. at 36. Counsel was unaware of the prohibition and inadvertently violated it in their motion for class certification. We regret the error and apologize to both the Court and Defendants.

Defendants correctly quote *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350 (2011), for the proposition that the existence of commonality “turns on ‘the capacity of a classwide proceeding to generate common *answers* apt to drive the resolution of the litigation.’” Opp. at 35. But when arguing that commonality does not exist, Defendants ignore the conspiracy allegations entirely. For example, again citing *Dukes*, they write that “class claims cannot be certified simply because a group of people have allegedly suffered similar resulting harms from individual wrongs allegedly done to each of them.” *Id.* at 37. Because *Dukes* did not involve a conspiracy, the quoted observation, although correct, is irrelevant. In *Dukes*, managers with delegated authority exercised discretion when making hiring decisions, which was “the opposite of a uniform employment practice that would provide the commonality needed for a class action; it [was] a policy *against having* uniform employment practices.” *Id.*

Here, by contrast, the Guardians allege that Defendants conspired to flood the United States with highly addictive drugs by changing the prescribing habits of physicians, concealing information, and other means. The evidence supporting these charges is the same for all class members. *Dukes* requires the Guardians to show that class members’ claims “depend upon a common contention” that is “of such a nature that it is capable of classwide resolution—which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke.” *Id.* at 350. The alleged conspiracy and the related violations of state and federal law are that “common contention.”

Defendants also distort the commonality requirement by attempting to build a predominance requirement into it. They quote the Court’s discussion regarding a potential class of persons diagnosed with NAS: “You’ve got to show how individual . . . combinations of fact predominate when you’ve got individual babies who were born of individual mothers, each of

whom had a difference chain of drug use.” *See* August 8, 2019 Hearing Tr. at 18, Doc. # 2151. The Court’s caution lodges a powerful objection to the certification of a personal injury class for damages under Rule 23(b)(3), which is what the Court was discussing at the time. The statement that “if all you’re seeking is medical monitoring, then say that and drop everything else” shows clearly the Court’s understanding that personal injury damages were being sought at the time. The Named Plaintiffs heeded the warning and seek to certify a class for medical monitoring only. Consequently, Defendants’ invocation of predominance is a not-so-subtle and improper attempt to interject predominance into the Rule 23(a)(2) commonality requirement.

The conspiracy allegation is the centerpiece of this litigation, and answers to questions of fact relating to it will resolve the major issues relevant to the Guardians’ claims,⁶ including whether a conspiracy existed, which Defendants participated in it, and whether its consequences included the improper prescribing of opiates to pregnant women and women who could become pregnant. The first two issues will be proven by common evidence relating to the conspiracy. The last will be established by means of evidence showing that Defendants improperly influenced prescribing guidelines, encouraged physicians to prescribe opiates to pregnant women, and expert testimony showing that the use of opioids by pregnant women and NAS births both vastly increased as the conspiracy continued.

C. The Named Plaintiffs are Adequate Class Representatives

⁶ The following questions, among many others, are common to all class members:

1. Did the Manufacturer Defendants conspire to conceal material facts, such as the potential of any dose of opioids to a pregnant woman to harm a developing fetus, the lack of product-safety testing concerning the effects of opioids on fetuses, and the heightened propensity of women (relative to men) to become addicted?
2. Did the Manufacturer Defendants conspire to influence physicians’ willingness to prescribe opiates to pregnant women and, if so, did they succeed?
3. Did all Defendants conspire to contribute, by acts and omissions, to overprescribing of opiates to pregnant women and women of child-bearing years and, if so, did they profit as a result?
4. Did all Defendants conspire to conceal the material knowledge that addiction, misuse, and diversion of opioids were rampant in the United States and, if so, did they profit as a result?
5. Was it foreseeable that the conduct at issue in Question 1-4 would harm children diagnosed with NAS in ways that necessitated expensive medical services in the short- and long-term?

Defendants contend that the Named Plaintiffs fail to meet the adequacy requirement set out in Rule 23(a)(4) because their claims “are subject to unique questions,” some of which are defenses. Opp. at 38. It turns out, however, that Defendants are using the adequacy requirement as an opportunity to reassert the false claim that the Named Plaintiffs are not class members. They write: “Plaintiffs’ theory *for classifying these individuals as members of the class* . . . would require application . . . of a multi-part, largely subjective expert analysis.” Then, they support this assertion with a cross-reference to Section I.A.1 of the Opposition, which discusses typicality. *Id.* As explained in § 2.A., *supra*, the Defendants’ typicality argument rests on their “Diagnosis+ re-draft” of the class definition. The objection to adequacy is based on the same ploy.

In fact, each representative meets the class definition and is a member of the class.⁷ Each is a guardian. *See* Poe Dep. at 32:17; Barnwell Dep. at 19:25-20:19; J. Ramirez Dep. at 30-31 (both parents legally married and living with child). Each representative cares for a child who had an NAS diagnosis that is documented in medical records.⁸ *See* Anand Supplemental Dec., Ex. A (Barnwell); Ex. B (Ramirez); Ex. C (Poe). Finally, each birth mother was prescribed opioids when pregnant. *Id.*

Defendants next contend that the Named Plaintiffs are inadequate because they lack standing to sue under RICO, 18 U.S.C. § 1961, *et seq.* Opp. at 39. One basis for this assertion is the contention that medical monitoring is not available as a remedy under RICO. Opp. at 28.

⁷ The Named Plaintiffs have also participated in the prosecution of the lawsuit. They have helped with fact investigation, participated in discovery and provided medical information, and testified in depositions. The Named Plaintiffs also uniformly hope to obtain injunctive relief. *See, e.g.*, J. Ramirez Dep. at 17-19, Ex. 26 at Bilek Decl., (explaining reason she chose to file a lawsuit against Defendants and describing the medical monitoring relief she hopes to obtain on behalf of the class); Barnwell Dep. at 16:13-23, 50:21-51:19 at Bilek Dec. Ex. 24 (explaining her decision to serve as a class representative and the need for medical monitoring she hopes to obtain through the lawsuit); Poe Dep. at 139-42, 145 at Bilek Dec. Ex. 25 (explaining how she decided to become involved in the lawsuit and the relief she is seeking in the suit).

⁸ Each child has also had successive NAS-diagnostic Finnegan scores greater than “8” and medication-assisted opioid therapy (i.e. pharmacological weaning) after birth. Anand Supplemental Dec., Ex. A (Barnwell); Ex. B (Ramirez); Ex. C (Poe).

Because the Court has already “conclude[d that Defendants’] argument that equitable relief is unavailable under RICO is not well-taken,” (Doc. # 2568, p. 10), it appears Defendants are rearguing a point they already lost.

True, Defendants add the wrinkle that “a ‘claim for medical monitoring is a claim for personal injury and not a claim of injury to business or property.’” Opp. at 29 (quoting *Fried v. Sungard Recovery Serv., Inc.*, 900 F. Supp. 758, 762 (E.D. Pa. 1995) and 39-40. They fail to note that in *Fried*, the persons who were exposed to asbestos were also the plaintiffs who suffered the alleged injuries and possessed the personal injury claims. Here, by contrast, no Guardian suffered NAS. All are suing because, as a result of Defendants’ actions, the Guardians must now provide expensive services for their wards, including monitoring aimed at driving early interventions.

After carefully reviewing the *Jackson v. Sedgwick Claims Mgmt. Servs., Inc.*, 731 F.3d 556 (6th Cir. 2013) line of cases, this Court concluded that RICO’s “business or property” requirement excludes liability “when the alleged RICO injury merely acts as an alternate theory for recovering damages otherwise available in a tort claim for personal injury and is asserted by the plaintiff him- or herself.” Doc. # 1203, at 14-15 (emphasis added). Here, no guardian suffered NAS. All are seeking injunctive relief, the purpose of which is to require the Defendants to bear costs that they would have to bear themselves to satisfy their legal responsibilities to care for their wards.

Citing *In re National Prescription Opiate Litig.*, 452 F. Supp.3d 745 (N.D. Ohio 2020), Defendants contend this Court was “hesitant” to recognize hospitals’ RICO standing to sue for unpaid medical bills and allowed claims to proceed only because they also asserted other damages theories. Opp. at 39-40. The analogy between hospitals and Guardians is much looser than Defendants contend. As the Court noted, hospitals can “seek compensation from the patients who are not paying those bills,” and patients include medical expenses in their damages cases. 452 F.

Supp. 3d at 769. Guardians have no claims against NAS Children, who cannot sue for damages either, first because they are minors, and second because what they need is injunctive relief.

Defendants continue their assault on the Named Plaintiffs' adequacy by contending that "none of them has any possible basis for claims against all of the named Defendants," and "[t]here are even some defendants. . . whom no proposed class representative has a potential claim." Opp. at 41-42.⁹ The premise here is the mistaken belief that a plaintiff can assert a claim only against a defendant with whom she personally interacted. It is well established that a person injured by any conspirator has standing to sue all conspirators, who are jointly and severally liable for the harms the conspiracy inflicts. *Salinas v. United States*, 522 U.S. 52, 64 (1997) ("[S]o long as they share a common purpose, conspirators are liable for the acts of their co-conspirators.").

The class representative's claims will be typical despite the presence of defendants with whom the representative has had no dealings if all of the defendants are linked by conspiracy, joint liability in tort, or some other relationship that constitutes more than simple commonality of the challenged conduct.

1 Newberg on Class Actions § 3:49 (5th ed.) (citing authorities).

When denying Defendants' summary judgment motions on similar issues, the Court has twice determined that sufficient evidence exists for a jury to find that Manufacturers and Distributors conspired with each other to expand the opioid market. *See* Order Regarding Defendants' Summary Judgment Motions on Civil Conspiracy Claims (Doc. # 2562) and Opinion and Order Regarding Defendants' Summary Judgment Motions on Causation (Doc. # 2561). Evidence of a conspiracy is common to all claimants. When presented in a class action, it can

⁹ Indeed, this is the main complaint of the separate Opposition filed by the Asserto Defendants which fails for the same reasons stated above. Doc. # 3522. Assertio, a manufacturer of opioids, is alleged to be part of the oversupply and diversion of opioid prescriptions that is at the very heart of conspiracy. Plaintiffs have been injured by the conspiracy and thus have standing to bring this action against Assertio. Regardless, Plaintiffs note that this is really a second attempt at a motion to dismiss or motion for summary judgment, which the Court refused to let them file. *See* May 11, 2020 non-document order in DAP Case No. 19-op-45459. Regardless, Plaintiffs request the right to add an additional class representative if in the unlikely event that this Court requires a class representative that purchased each opioid manufacturer's product.

establish both the existence of a conspiracy and the identities of the conspirators for the benefit of all. This is why “courts have noted that claims arising under RICO statutes. . . are often particularly appropriate for class action treatment.” 1 Newberg § 3:24 (citing authorities).

Defendants’ final adequacy challenge is that the interests of the Guardians’ and the absent class members conflict because a class limited to injunctive relief “could preclude class members from later seeking. . . damages under principles of res judicata, including the bar on claim-splitting.” Opp. at 44. Because “dozens of potential class members have pending claims for damages,” the Named Plaintiffs are “jeopardiz[ing] class members’ ability to bring those claims.” *Id.*

The Sixth Circuit made short work of this concern in *Gooch v. Life Investors Ins. Co. of America*, 672 F.3d 402, 429 n.16 (6th Cir. 2012) (internal citations omitted):

Piecemeal certification of a declaratory-relief-only class does not present a problem of preclusion for class members who wish to pursue damages claims. “[A] class action, ‘of course, is one of the recognized exceptions to the rule against claim-splitting.’” “Pursuant to the same general principle that claim preclusion does not apply to matters that could not be advanced in a prior action, individual actions remain available to pursue any other questions that were expressly excluded from the class action.”

The Supreme Court reached the same conclusion in *Cooper v. Fed. Reserve Bank of Richmond*, 467 U.S. 867 (1984). There, after a class action alleging employment discrimination failed to secure monetary relief, some class members sued on individual claims of discrimination. The Supreme Court allowed their individual actions to proceed. Although the judgment against the class “bar[red] the class members from bringing another [class action or individual lawsuit] against the Bank alleging a pattern or practice of discrimination,” it was “not [] dispositive of the individual claims [] alleged in their separate action,” despite being factually related. *Id.* at 880.

“The principle that a ‘class action suit seeking only declaratory and injunctive relief does not bar subsequent individual damage claims by class members, even if based on the same events,’

is well established.” *Nelson v. Wal-Mart Stores, Inc.*, 245 F.R.D. 358, 372 (E.D. Ark. 2007) (quoting *Hiser v. Franklin*, 94 F.3d 1287, 1291 (9th Cir. 1996)); see also *In re Jackson Lockdown/MCO Cases*, 568 F. Supp. 869, 892 (E.D. Mich. 1983) (every court considering the question “held that a class action seeking only declaratory and injunctive relief does not bar subsequent individual suits for damages based on the same or similar conditions.”).¹⁰

Adding a wrinkle to the argument just described, Defendants also accuse the Named Plaintiffs of violating the *Amchem* prohibition on combining persons with manifest injuries and future claimants into a single class. *Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 625-626 (1997). This contention fails for the same reason: The Named Plaintiffs’ seek only injunctive relief for the class. Because there will be no need to allocate limited relief between present and future claimants, no *Amchem* problem can arise.

III. THE CLASS DEFINITION IS LEGALLY SUFFICIENT

Per Rule 23(c)(1)(B), “[a]n order that certifies a class action must define the class.” Caselaw establishes that the class definition must be precise, objective, and presently ascertainable. The Manual for Complex Litigation, Fourth, § 21.222 (emphasis added) states:

Although the identity of individual class members need not be ascertained before class certification, the membership of the class must be ascertainable. Because individual class members must receive the best notice practicable and have an opportunity to opt out, and because individual damage claims are likely, Rule 23(b)(3) actions require a class definition that will permit identification of individual class members, while Rule 23(b)(1) or (b)(2) actions may not. *An identifiable class exists if its members can be ascertained by reference to objective criteria.* The order defining the class should avoid subjective standards (e.g., a plaintiff’s state of mind) or terms that depend on resolution of the merits (e.g., persons who were discriminated against).

¹⁰ The Court can also address any concerns about depriving absent guardians of their damages claims by allowing them to opt out. *McReynolds v. Richards-Cantave*, 588 F.3d 790, 800 (2d Cir. 2009) (“[T]he language of Rule 23 is sufficiently flexible to afford district courts discretion to grant opt-out rights in (b)(1) and (b)(2) class actions.”) (internal quotation marks omitted).

The proposed class definition meets this standard. Membership in the class is established on the basis of documentary evidence: guardianship of a ward; a diagnosis of NAS at birth; a prescription for opioids received by the birth mother before the birth; or more narrowly, a prescription received during the pregnancy. If the class wins, these criteria can easily be used to determine eligibility to participate in the medical monitoring program. And if the class loses, they can be used in later suits to determine whether claims are precluded by *res judicata*.

IV. THE REQUIREMENTS FOR CERTIFYING AN INJUNCTIVE CLASS ARE MET

The Rule 23(a) challenges¹¹ completed, Plaintiffs address Defendants' objections to certification of an injunctive class under Rule 23(b)(2).

A. Defendants Conspired to Flood the U.S. with Improperly Prescribed Opioids and Acted on Grounds That Apply Generally to the Class

Defendants correctly note that "Rule 23(b)(2) requires a showing that 'the party opposing the class has acted or refused to act on grounds that apply generally to the class.'" Opp. at 57. Unfortunately, they repeat their prior erroneous contention that the Named Plaintiffs can only sue Defendants they interacted with personally and ignore the law of joint liability for conspirators: "so long as they share a common purpose, conspirators are liable for the acts of their co-conspirators." *Salinas*, 522 U.S. at 64. The conspiracy alleged by Plaintiffs and the common harm it caused them are the Rule 23(b)(2) "grounds that apply generally to the class."¹²

B. Plaintiffs Will Offer Common Proof of Conspiracy, Causation, Harm, and the Efficacy of Medical Monitoring

¹¹ There was no challenge regarding numerosity nor competency of counsel, which were otherwise established by Plaintiffs' motion. Opposition, *passim*

¹² "The defining characteristic of 23(b)(2) classes is the 'homogeneity of the interests of the members of the class.'" *Reeb v. Ohio Dept. of Rehab. and Correction*, 435 F.3d 639, 649 (6th Cir. 2006). As such, where individualized assessments are required, the requisite homogeneity needed to protect the interests of absent class members is lacking. *Id.*" *Gawry v. Countrywide Home Loans, Inc.*, 640 F. Supp. 2d 942, 960 (N.D. Ohio 2009), *aff'd*, 395 F. App'x 152, 153 (6th Cir. 2010).

Plaintiffs' theory of liability and common proof arising from Defendants' conspiracy is the same for each class member, as illustrated below:

Step 1: Improper prescription of addictive, high-risk opioids to Birth Mother (either while pregnant or when she can become pregnant)

Step 2(a): Addictive, high-risk opioids supplied to Birth Mother

Step 2(b): Creation, support of, and supply of illegal diversionary market for those same addictive opioids prescribed and supplied to the Birth Mother

Step 3: Birth Mother supplies her growing dependency on opioids* through more improper prescriptions and/or the Illegal diversionary market

Step 4: Return and Repeat ∞ Including During Pregnancy

Step 5: The Plight of the At-Risk NAS Children and the Guardians Who Care for Them who Share the Same Interests and Same Claims with Each Other

***In the loop of addiction, improper prescriptions and the illegal diversionary market both have a causal effect—supply creates demand and demand creates supply**

1. Defendants Acted and Refused to Act on Grounds Generally Applicable to the Class

Defendants spend only one-sentence arguing that the Named Plaintiffs have failed to show that Defendants acted on grounds generally applicable to the class. Opp. at 57. Notably, every Rule 23(a)(2) common question identified by Plaintiffs (infra, at “Commonality,” § II.B, n.5) is a matter on which Defendants collectively acted and refused to act, and contrary to Defendants' allegations, none of them “depend on what medications the birth mother took, where she got those medications, and who supplied them.” *Id.* Defendants conspired to destroy the previously safe and appropriate system for prescribing and controlling prescription opioids in the U.S., including to pregnant women and women who could become pregnant. This conspiracy resulted in a tsunami of NAS births and irrevocably altered the duty of care owed by the Guardians and NAS Children. Certification under 23(b)(2) is entirely appropriate and warranted.

2. Common Proof of Conspiracy

The factual matter of Defendants' conspiracy is not new to this Court. It has written numerous opinions in the MDL on motions to dismiss and for summary judgment which detail evidence of Defendants' wrongful conduct of marketing and distribution of opioids. At trial Plaintiffs will offer other and further evidence of the conspiracy which relate solely to their claims, all of which are set out in their Common Issues, and which include, but are not limited to: (1) Defendants marketed their products knowing there is no safe dose of opiates for a fetus that can be prescribed to a mother during pregnancy;¹³ (2) Defendants marketed their products knowing there was little product-safety testing for opioids in regards to a fetal exposure;¹⁴ (3) Defendants improperly influenced the CDC's national prescribing guidelines for acute and chronic pain, while also concealing through their marketing that these same guidelines do not address differences in prescribing to women and do not apply at all to pregnant women;¹⁵ (4) Defendants improperly concealed that the risk/benefit analysis for prescribing opioids to women must account for (a) unique gender differences, including significantly higher rates of addiction, faster addiction, addiction at lower dosage, and higher rates of misuse,¹⁶ and (b) must also account for the significant risk of long-term adverse effects of *in utero* opioids exposure;¹⁷ and (5) Defendants worked collectively to suppress the true nature of the prescribing rates of opiates to pregnant women and women as who could become pregnant, as well as the size and scope of the diversionary market, in order to conceal the causal connection between prescription opioids and the growing epidemic of NAS births.¹⁸ Further acts in support of the conspiracy include improper

¹³ Anand Report, Ex. 5, Dann Dec.to Consolidated Motion for Class Certification. Doc. # 3067.

¹⁴ *Id*

¹⁵ Bilek Dec. at Ex. 9 and Ex. 5, Porucznik Dep., 66:2-13, 83:23-25, and 84:8-11.

¹⁶ Bilek Dec. at Ex. 6, Wright Dep., 26:18-21, 27:13-16, 33: 5-8, and Ex. 5 Porucznik Dep., 83:23-26, 84:8-11, and Ex. 15 and Anand Supp. Dec. at Ex. I.

¹⁷ Anand Report, Ex. 5 of Dann Decl. (Doc. # 3067) and Anand Supp. Decl. at Exs. B-G, K, and O.

¹⁸ The acts in furtherance of the conspiracy to create and maintain the diversionary market are already before this Court in *Summit County*.

payments to physicians to promote opioids and/or prescribe opioids¹⁹ and improper payments to CDC advisory committee members whose job was to advise the CDC on guidelines for the prescribing of opioids.²⁰ As a result, it was impossible for any physician in the U.S. to undertake a correct risk/benefit analysis in prescribing an opioid due to Defendants' misrepresentations and concealment of material facts, and all prescriptions were materially affected by the conspiracy.

3. Common Proof of Causation

The most obvious common proof that Defendants have previously conspired to mislead the about opioids and the significant specialized risks they pose to women and to fetus is that they are currently repeating these exact same dangerous, erroneous, and unsubstantiated claims in defense of the instant lawsuit. Just as they previously suppressed material facts and made misstatements about (a) that substances other than opioids were actually causing the massive spike in NAS births in the U.S. and (b) that there is a significant risk of long-term adverse health consequences from NAS, they make the same arguments to this Court. *Opp.*, *passim*.

Contrary to their false marketing, NAS is a most unique medical condition that is caused by withdrawal from opioids. The two experts Defendants offer on the subject of medical causation of NAS, Lewis P. Rubin, M.D. and Henry C. Lee, M.D., both explained the link between the medical diagnosis of NAS and legal causation in this case which is achieved by the class definition. Rubin testified: “[W]hen a woman is taking a prescribed opioid and she has a child that is born with NAS, that prescription would be a cause of the NAS in the child? Yes. [T]he proximate cause of the NAS, perhaps you could say, is that the prescription was written[.]” Bilek Dec. at Ex. 4,

¹⁹ One of twelve doctors in America received some form of payment from a pharmaceutical company that resulted in physicians improperly increasing their prescribing of opioids. These “marketing” payments were nothing more than kickbacks. Bilek Dec. at Ex. 14.

²⁰ Bilek Dec. at Ex. 19 and 20. This unethical conduct continues to this day. Indeed, Defendants have hired and paid for an expert report of an epidemiologist, Dr. Christina Porucznik, who is the newest Chairman of the Advisory Committee on Opioid Prescribing Guidelines to the CDC. Bilek Decl., at Ex. 5, Porucznik Dep., at 12:25, 13:1-3 and 5-10.

Rubin Dep., 68:5-21 (emphasis added). Lee echoed: “If they had a prescription to opioids [during pregnancy] and the constellation of symptoms were consistent with what we know about NAS, we would call that NAS.” Bilek Dec. at Ex. 3, Lee Dep., 175:15-19. The precisely crafted definition excludes from the monitoring protocol the hypothetical, but nearly implausible possibility promoted by Defendants, of an NAS-diagnosed child born during the Opioid Crisis who had no exposure at all to opioids.

Defendants conjure up a chart of alleged “Examples of Non-Opioid Substances that Can Cause NAS” that is unsupported by their expert’s reports (the sole authority they cite), the medical literature, or the record in the case. Opp. at 5. Regardless, the medical literature on both NAS and polysubstance exposure overwhelmingly concludes that other substances are additive to and increase the severity of NAS arising from opioids, but do not cause it in isolation. Dr. Anand testified at length on the matters of causation of NAS.

Q: Do you have a sense as to what degree those other substances, if present, or if used by the mom, contribute to the symptomatology of a baby born with NAS?

A: They certainly do, although the symptomology of NAS is quite distinct from the withdrawal syndrome from some of those other drugs. . . [NAS is] a constellation of neurological excitability, gastrointestinal disturbances and autonomic instability, and that entire constellation comprises NAS. Opiates. . . are depressant drugs. They reduce neuronal excitability. And where some of these other drugs, methamphetamine, . . . cocaine, these are all stimulant drugs, so the syndrome they produce from withdrawal is quite different.

Bilek Dec. at Ex. 2, Anand Dep., 189-90;16-25 and 1-15. As to benzodiazepines potentially causing NAS in isolation, Dr. Anand explains:

You mentioned benzodiazepines. Now, benzodiazepine is also a depressant, similar to opiates, but the benzodiazepine withdrawal that is seen is quite different from opiate withdrawal. . . [Y]ou have a flapping-like tremor. In opiate withdrawal, you have a fine tremor. In benzodiazepine withdrawal and opiate withdrawal, you both have insomnia, but in opiate withdrawal. You have hypertonicity, muscle tone is increased and the deep tendon reflexes are hyperreflexic, whereas in benzodiazepine withdrawal, it’s the opposite. Muscle tone is decreased. They are actually the floppy infants. And their deep tendon reflexes are also suppressed. So there are ways of differentiating benzodiazepine withdrawal from

opiate withdrawal even though both of these are sedatives. However, in benzo withdrawal, you don't get any gastrointestinal problems. There is none of the sucking, swallowing, dysphagia, retching, vomiting, diarrhea, abdominal cramping, all of those things just don't occur. So those are different syndromes clinically and that's why NAS, as it is described in the literature, it's important to establish that clinical diagnosis.

Id. at 190-91: 16-24 and 1-21. Defendants have no support for their contention that benzodiazepine-only exposure is causing NAS. Opp., *passim*. Polysubstance exposure is equally not a valid concern, because those other substances are only additive and worsening to the effect of the opioids.²¹ Dr. Anand explains:

The babies that will manifest with NAS, if they're occurring in the setting of other substances being abused, will clearly show signs of NAS, and I'll tell you why. When you give these things together, when you give opiates, you give, say, oxycodone, and you give benzodiazepine or alcohol or methamphetamine or Ketamine or all these other drugs, they accelerate the rate at which tolerance occurs to the opiate. . . Giving opiates does not increase the rate of tolerance to these other drugs, whereas these other drugs increase the rate of tolerance to opiates. And that's been shown in the lab in, you know, various other different experimental symptoms. **So that's why, if there is an exposure and you're seeing signs and symptoms of NAS, it is the opiate withdrawal that is the most prominent aspect. And you'll see all of the [NAS] constellation that I mentioned. . . And it's fairly clear to any clinician to make that diagnosis.**

Id. at 192-94; 13-24, 1-13, and 8-10 (emphasis added). Defendants' arguments also ignore the fact that most NAS Children at issue in the class also have multiple and additional objective indicia of opioid exposure because they were (a) pharmacologically weaned with opioids, (b) tested positive for opioids at birth, (c) received opioid-specific diagnostic codes for NAS/NOWS at birth; and/or (d) the birth mother was diagnosed with OUD, dosed with opioids while birthing, and/or admitted to concurrent opioid usage in connection with the delivery of the NAS Child, all of which is subject

²¹ As a gentle reminder to Defendants, their own experts conceded that the additive and worsening effect of other substances is irrelevant both to legal causation and the question of typicality of Putative Class Representatives. As Dr. Rubin readily admitted without qualification: "[T]he proximate cause of the NAS, perhaps you could say, is that the prescription was written[.]" Bilek Dec., Ex. 4, Rubin Depo., 68:5-21 (emphasis added). Defendants' other neonatologist, Henry C. Lee, M.D. said almost the exact same thing and also without qualification, testifying: "If they had a prescription to opioids [during pregnancy] and the constellation of symptoms were consistent with what we know about NAS, we would call that NAS." Bilek Dec., Ex. 3, Lee Dep., 175:15-19. This is true even if a birth mother also smoked a cigarette, drank a beer, or took a benzodiazepine during pregnancy.

to mechanical review of hospital records. See Anand Report, Ex. 5 of Decl. of Marc Dann, Doc. # 3067.²²

The nullity of Defendants' hypothetical of a non-opioid-exposed, NAS-diagnosed child who might fall under the monitoring and surveillance protocol (which is an attack on common proof of causation) is also entirely inconsistent with recent medical statements about NAS and the medical literature. This month the American Association of Pediatricians (AAP) published its long-awaited "Guidance for the Clinician in Rendering Pediatric Care"²³ in which it explains to treating physicians the cause of NAS/NOWS, how to care for diagnosed children at birth, and is based on the totality of up-to-date medical literature on NAS. Explaining the causal link between the Opioid Crisis and NAS, the AAP states:

As the opioid crisis grew in scope and complexity in the population at large, opioid use and opioid use disorder (OUD) among pregnant women also increased. Opioid use in pregnancy can lead to a withdrawal syndrome in the newborn shortly after birth. The syndrome has been traditionally called neonatal abstinence syndrome but more recently has been called neonatal opioid withdrawal syndrome (NOWS) by federal agencies, including the US Food and Drug Administration. Although neonatal abstinence syndrome is a more general term for neonatal withdrawal that, in the literature, may include nonopioid exposures (eg, benzodiazepines), evidence suggests that the recent growth of neonatal drug withdrawal has been primarily from in utero opioid exposure either in isolation or in combination with other substances.

Increases in maternal opioid use were accompanied by a parallel increase in NOWS. From 2000 to 2016, the incidence of NOWS increased from 1.2 to 8.8 per 1000 hospital births. These increases have been steeper in rural and tribal areas, and among infants enrolled in the Medicaid program.

NOWS is a major consequence of the opioid crisis, with dramatic increases over the last decade.

²² Dr. Anand's report filed with the Court contains a typo, which he corrected, but then failed to provide to putative class counsel for filing with the Court. Instead, the older, incorrect version was forwarded for filing. For the five objective diagnostic criteria for NAS, Dr. Anand explained to Defendants on the record a few weeks after the report was filed, that the criteria are alternative, not additive, and that he had corrected the report to change the "and's" to "or's." Bilek Dec., Anand Depo., Ex. 2, 203-04; 1-24 and 1-7 ("Q: So if a baby is—meets any of these conditions, then that baby would be monitored; is that correct?" A: That is correct." *Id.* 204:19-22).

²³ Stephen W. Patrick, Wanda D. Barfield, Brenda B. Poindexter and COMMITTEE ON FETUS AND NEWBORN, COMMITTEE ON SUBSTANCE USE AND PREVENTION, Neonatal Opioid Withdrawal Syndrome, *Pediatrics* 2020;146, Oct. 26, 2020, at 1-2.

Id. The AAP also squarely addresses the strawman issues of other substances solely causing NAS or polysubstance use that are raised by Defendants, stating: “Opioid use typically does not occur in isolation and frequently involves other substances.” *Id.* Continuing: “Importantly, use of other substances (eg, tobacco) or prescription sedatives (eg, benzodiazepines) along with an opioid **may increase risk and/or severity** of NOWS.” *Id.* at 2 (emphasis added). Defendants’ hypothetical of the non-opioid exposed child falling under the class definition cannot arise where, as here, there is (1) a definitional requirement of the birth mother’s opioid prescription history and the (2) entirely non-coincidental facts that (a) that same woman with that prescription history (b) gave birth to a child with NAS/NOWS which is almost always caused by opioids (c) during the Opioid Crisis. Simply put, causation can be established by common proof.

4. Common Proof Regarding Injunctive Medical Monitoring for the Long-Term Adverse Effects of NAS

Plaintiffs have certainly provided “some” evidence favoring the underlying class claim for injunctive medical monitoring relief by showing the high risk of adverse long-term health effects for NAS-diagnosed Children. *See Dukes*, 564 U.S. at 350-51 (the moving party should provide “some” evidence favoring the underlying claims).

Defendants do not challenge Dr. Anand’s qualifications to render his opinions that all children diagnosed with NAS need injunctive monitoring and surveillance, nor the medical and scientific basis for those opinions.²⁴ *Opp.*, *passim*. And, indeed, Defendants’ efforts through their own experts to offer contravening expert opinion on the risk of long-term adverse health effects from NAS has been spectacularly unsuccessful. *See Summary of Key Defense Expert Deposition*

²⁴ For the ease of this Court and any reviewing court, Plaintiffs have marshalled the “hot docs” relied upon by Dr. Anand in forming his opinion and/or used to cross-examine Defendants’ medical experts. *See Anand Supp. Dec.*, at Ex. A-U.

Testimony at Bilek Dec., Ex. 1. Two of Defendants experts (Wright and Porucznik) claim significant reliance on a study that (a) has been reversed and (b) now stands exactly for Plaintiffs' case:²⁵

During our entry of raw data[], we transposed one of the columns of data. This meant the values generated by all the meta-analysis and results produced in the published manuscript were incorrect. The new conclusions of the paper show significant impairments at significant level. . . for cognitive, psychomotor, and observed behavioral outcomes for chronic intrauterine opioid exposed infants and/or preschool children compared to nonopioid exposed infants and children.

Defendants' similarly fail to disclose to the Court that **while acting as an expert in this case in June, 2020**, Dr. Rubin edited and approved for publication a scientific study which finds that: ²⁶:

The incidence of opioid abuse in the United States has steadily increased since 2000, today reaching epidemic proportions. The crisis is illustrated by data demonstrating that the number of opioid-related hospitalizations increased by 64%, and the number of deaths due to opioid overdose increased by 27% between the years of 2005 and 2014. Mirroring the national trend, opioid use by pregnant women has escalated to alarming rates. Opioid use in this population increased 5-fold from 2000 to 2009, and the prevalence of women with opioid use disorders at delivery hospitalizations quadrupled between 1999 and 2014.

The devastating consequences of opioid exposure are the physical health and developmental outcomes of exposed children and strengthen the need to advance scientific understanding of the underpinnings of opioid-induced neural injury and to advance biomarker development of this patient population.

Recent studies showing an association between opioid use during pregnancy and poor health outcomes for both pregnant women and infants highlight prenatal opioid exposure as a serious public health concern.

Prenatal opioid exposures are associated with an increased risk of . . . lifelong motor and cognitive deficits.

²⁵ Anand Supp. Decl., Exh B, Baldacchino, A., *et al.* "Erratum: Neurobehavioral Consequences of Chronic Intrauterine Opioid Exposure in Infants and Preschool Children: A Systematic Review and Meta-analysis. *BMC Psychiatry* 15, 134 (2015). <https://doi.org/10.1186/s12888-015-0438-5> (emphasis added). Neither Wright, nor Porucznik corrected their reports before they were filed with the Court, nor did Defendants notify the court of the error, even though **Porucznik stated at her deposition that the report would have to be corrected because "that's how science works."** Bilek Decl. at Ex. 5, Porucznik Depo., 98:1-2, 99:12-16.

²⁶ Anand Supp. Dec., Ex. Q, "Perinatal Opioid Exposure Primes the Peripheral Immune System toward Hyperreactivity," Newville, J. et al, *Frontiers in Pediatrics*, June 2020 8:272 (Lewis P. Rubin, M.D., Editor).

(Emphasis added). Asked to try to reconcile the contradictions, Rubin would only say: “[Y]es, I’m the editor. Yes, my name is on here and yes, I agree with this paper.” Bilek Dec. at Ex. 4, Rubin Depo., 254:14-16.

Defendants similarly claim that the report of their expert Dr. Lee stands for the proposition that there should not be medical monitoring of the NAS Children at issue. That is not what Lee testified to and, indeed, he has published articles which advocate that “longer-term health and neurodevelopmental outcomes” of NAS Children “be tracked.”²⁷ Lee freely admitted at this deposition that **based on the studies provided to him by Plaintiffs’ counsel** and studies he cited in his own report: “I think, just as these other researchers have done in the studies that. . .you have presented today and also in my report, we can continue to study whether NAS or other associated factors may be related to outcomes that are beyond the newborn period.” Bilek Dec., Ex. C, Lee Dep., 168:10-15.

None of Defendants’ experts cites or tries to distinguish in their reports an extremely important new meta-analysis in which the authors analyzed 26 other studies on the long-term effects of NAS and controlled for a wide variety of potential confounders to determine that impaired cognitive and motor outcomes were the causal result of exposure to opioids. The authors summarized their “study of studies” succinctly, stating:²⁸

Question Is prenatal opioid exposure associated with differences in childhood cognitive and motor development?

Findings In this systematic review and meta-analysis of 26 studies including 1455 children exposed to prenatal opioids compared with unexposed children, prenatal opioid exposure was associated with lower cognitive scores. The largest difference was seen between ages 6 months and 6 years.

²⁷ Bilek Dec. at Ex. 3, Lee Dep., 168:4-8, *citing* Lee Dep. Ex. 15, attached at Anand Supp. Decl, Ex. C.

²⁸ Anand Supp. Decl., Exh O, “Cognitive and Motor Outcomes of Children with Prenatal Opioid Exposure: A Systematic Review and Meta-analysis”, Yeoh, S.L. *JAMA Netw Open*. 2019;2(7):e197025. doi:10.1001/jamanetworkopen.2019.7025.

Meaning The negative consequences of prenatal opioid exposure on neurocognitive and physical development appear to be present from 6 months and persist beyond school age.

And, finally, though the AAP Clinical Guidance was issued after the filing of Defendants' Opposition, it is impossible for them to counter the AAP's findings on necessary monitoring and surveillance. The entirety of the AAP Guidance is premised on the notion that an NAS diagnosis²⁹ is the triggering event for monitoring and surveillance and that there does not need to be an additional assessment beyond the diagnosis. It is also critical to recognize that the AAP recommends the monitoring and surveillance relief requested by the NAS Guardians, which is not part of standard pediatric care.

In addition to developmental, behavioral, and mental health screenings by the primary care pediatrician, all infants with substance exposure should be referred to early intervention services, and developmental screenings in a NICU developmental assessment clinic or equivalent should be considered. Anand Supp. Dec. at Ex. K., at 10 (emphasis added). And, contrary to Defendants' assertions, the AAP also concludes that monitoring and surveillance for the specific risks of the NAS must occur even though a child might be subject to future "social and economic factors" that "may adversely affect infant development[.]" *Id.* at 2. The AAP states without qualification that "[m]ore research to support the optimal assessment of an infant with opioid exposure is needed." *Id.* at 5. And on polysubstance use, the AAP recognizes that other substances are **additive** to NAS, i.e., they "may increase risk and/or severity," for NAS. *Id.* at 2.

It is beyond cavil that Defendants have not mounted enough of a challenge to defeat Plaintiffs' showing of "some" certification proof through their experts, especially where, as here, Defendants have absolutely waived the right to do so by not challenging that expert proof in their

²⁹ Indeed, the AAP concludes that this must occur in all cases of opioid exposure, even those that present at subclinical levels that would not result in an NAS diagnosis, and regardless of whether the child was also exposed to other substances. *Id.* at Ex. K. Plaintiffs' class is much more narrowly tailored.

Opposition. Opp., *passim*. Plaintiffs have established a basis for common proof of liability, causation, and remedy.

C. The Proposed Class is Cohesive

Defendants next contend that the proposed (b)(2) class lacks cohesion because the request for injunctive relief “limits the rights of claimants and future claimants by prescribing a one-size-fits-all relief for all class members.” Opp. at 57. What they mean by this is not clear. A medical monitoring program will provide assessments for all NAS-diagnosed children that will indicate whether they are experiencing certain adverse consequences related to in utero opioids exposure and, for those who are, will recommend appropriate treatments. Under Defendants’ misapprehension of monitoring and surveillance, the results of the protocol are conflated with the protocol itself. The protocol is the same for each child. What will vary are the results.

Defendants press their objection further by arguing that cohesion exists only when litigation of class members’ claims “will not depend on adjudication of facts particular to any subset of the class.” Opp. at 58. Although they cite several cases for this proposition, they never show that adjudication focusing on any subset of the guardians will be required. Given that the validity of all Guardians’ claims turns on proof of the conspiracy, which is common to all, it seems clear that no such focus will be required. Hoping to convince the Court otherwise, Defendants contend that a host of individualized issues prevent (b)(2) certification, including children’s “circumstances of exposure,” “short[-] and long-term effects,” and “facts that might or might not make one or more defendants culpable.” *Id.* The “facts that might or might not make one or more defendants culpable” will be established by proving that a conspiracy existed, and that (some or all) Defendants participated in it. Children’s “circumstances of exposure” will be established by showing that the birth mothers of the NAS-diagnosed Children all had prescriptions for opioids.

The effects of opioid exposure *in utero* will be shown for all guardians by means of expert testimony based on competent evidence. Only when and if liability to the class is established, will the Court design a program of injunctive relief based upon recommendations from experts in relevant fields.

D. The Court Can Certify a California Class for Injunctive Relief

1. California Law Allows for Medical Monitoring

Defendants admit that California has a long history of medical monitoring claims. *Potter v. Firestone Tire & Rubber Co.*, 861 P.2d 795, 824-25 (Cal. 1993). To pursue a medical monitoring claim, Plaintiffs need not even establish that future injury is probable. *Id.* Likewise, Defendants do not dispute that guardians have the fiduciary duty to bring these claims for medical monitoring. *See* Doc # 3066, at 51.

Defendants outline the five relevant factors that courts consider in determining if “the need for future monitoring is a reasonably certain consequence of a plaintiff’s toxic exposure and that the recommended monitoring is reasonable,” which is the standard for medical monitoring. *Opp.* at 27, citing *Potter*, 861 P.2d at 864. As shown below, contrary to Defendants’ assertions, each factor is common to the class and dictates in favor of class certification.

With respect to the first *Potter* factor, the significance and extent of the exposure to chemicals, plaintiffs’ experts have explained that in the context of opiate use and NAS, the specific exposure to opioids for each individual birth mother is not relevant, as long as she received a prescription for opioids and her child was diagnosed with NAS (class requirements). As to the second factor, toxicity of chemicals, each child, by definition, suffers from NAS, and as such, no individual inquiry is necessary. Each child has already suffered physical symptoms (symptomatic NAS) caused by opioids. The third factor, the relative increase in the chance of onset of disease in the exposed plaintiff compared to a non-exposed plaintiff or the public at large, is once again, the

subject of expert testimony that is uniform for each of the NAS children. The last two factors, the seriousness of the disease and the clinical value of early detection are also common factual issues for each of the NAS children, as plaintiffs' experts have shown.

Lockheed Martin Corp. v Superior Court, 63 P.3d 913 (Cal. 2003), which is distinguishable on crucial facts that led the California Supreme Court to reverse class certification, supports class certification here. *Lockheed* was a putative class action seeking medical monitoring and punitive damages for negligent discharges of dangerous chemicals into resident class members' groundwater. As an initial matter, plaintiffs in *Lockheed* were seeking certification under 23(b)(3) arguments since the plaintiffs were making claims for individual compensation for personal injuries. The Guardians are seeking certification primarily under (b)(2) for the abatement of this crisis. In *Lockheed*, the class reversed because the court found that the plaintiffs failed to establish predominance, something that is not required in a (b)(2) class.

Even under the *Lockheed* analysis, certification would be proper and the Guardians have established predominance. Defendants must admit that the *Lockheed* court explained that "no per se categorical bar exists to a court's finding medical monitoring for class treatment, so long as individual issues in the claims present are manageable." *Id.* at 919. It added that "[w]e consistently have recognized, before and after *Potter*, that the fact that each member of the class must prove his [or her] separate claim to a portion of any recovery by the class is only one factor to be considered in determining whether a class action is proper." *Id.* at 918.

In addressing the class motion in *Lockheed*, the court first ruled that the issue of duty of care is a question of law that can be susceptible to common proof. Similarly, here the question of whether the defendants, who allegedly conspired to create the opioid crisis that has damaged each putative class member, is a common question of law. Next, the court held that how and when

defendants disposed of toxic chemicals, and whether such conduct was negligent, were significant common issues of fact. Similarly, defendants' actions here, are common issues of fact. With respect to the final negligence element, causation, the *Lockheed* court held, as here, that "the toxicity of the chemicals," and "the seriousness of any disease for which the plaintiff is at risk...would be susceptible of common proof." *Id.* at 920.

The *Lockheed* court then relied on factors clearly not present in this case to reverse class certification, ruling that each class member's individual dose was a crucial issue, as plaintiffs' experts could not confirm that each received a dose exceeding minimal levels to require medical monitoring, and prove damages and causation. Additionally, the court ruled that "whether an individual class member needs additional medical monitoring depends heavily on numerous factors specific to that individual..." *Id.* at 925. As such, the *Lockheed* court ruled that plaintiffs could not show predominance. By contrast to *Lockheed*, dose here is not relevant to showing that the NAS children have suffered an injury sufficient to justify medical monitoring, because whatever their dose, it was more than sufficient to cause NAS. Moreover, once the child has been diagnosed with NAS, the protocol for medical monitoring is uniform.

2. California Law of Conspiracy

It is also well-settled under California law that each participant in the wrongful conspiracy is responsible as a joint tortfeasor for all damages ensuing from the wrong, regardless of the degree of his activity. *Berg & Berg Enterprises, LLC v. Sherwood Partners, Inc.*, 131 Cal.App.4th 802, 823 (2005) ("Each member of the conspiracy becomes liable for all acts done by others pursuant to the conspiracy, and for all damages caused thereby.") *See also Applied Equipment Corp. v. Litton Saudi Arabia Ltd.*, 7 Cal.4th 503, 510-511 (Cal. 1994) (conspiracy is "a legal doctrine that imposes liability on persons who, although not actually committing a tort themselves, share with

the immediate tortfeasors a common plan or design in its perpetration".) Thus, Plaintiffs have standing to sue all conspirators. Defendants also erroneously argue that plaintiffs who did not purchase from co-conspirator defendants are precluded from filing class claims against those co-conspirators, is erroneous. "A plaintiff injured by one defendant as a result of the conspiracy has standing to represent a class of individuals injured by any of the Defendant's co-conspirators." *In re NASDAQ Market-Makers Antitrust Litigation*, 169 FRD 493, 508 (S.D.N.Y. 1996). All defendants are equally responsible to each class member because, among other things, they conspired to create the diversionary market and oversupply opioids to Americans that resulted in each class member's injuries.

3. The California UCL

Defendants' arguments regarding the UCL claims are equally unavailing. California UCL, Section 17204 of the California Business Code authorizes actions for relief by any person who has suffered injury-in-fact and has lost money or property as a result of the unfair competition. The UCL expressly provides for injunctive and other equitable relief to remedy the unfair practices, including disgorgement of profits. In *City & Cty. of S.F. v. Purdue Pharma L.P.*, No. 3:18-cv-07591-CRB, 2020 U.S. Dist. LEXIS 181274 (N.D. Cal. Sep. 30, 2020), a case transferred out of this MDL, Judge Breyer denied motions to dismiss various California state law claims, including UCL, against these same Defendants. Defendants do not cite the opinion, nor try to distinguish it. Opp., *passim*. Necessarily finding standing, Judge Breyer held that Defendants' conduct, if established at trial, would violate the UCL. The Guardians assert the same claims and have also UCL standing.³⁰

³⁰ In *In Re Tobacco II Cases*, 46 Cal.4th 298 (Cal. 2009), the California Supreme Court addressed the issue of standing under the UCL. It held that the class representative must show that he has suffered injury in fact and lost money or property as the result of such unfair competition. Specifically, the plaintiff must establish that the injury was an

Defendants' arguments that the Guardians cannot establish class wide causation under California law is likewise without merit and Judge Breyer's opinion is especially instructive. The public nuisance claims at issue there require a showing of causation in fact, i.e. that the bad acts were a substantial factor in bringing about the result, and were also not too remote. Breyer concluded that for causation, defendant's conduct must be necessary in bringing about the full extent of the injuries. Breyer concluded that the allegations met this standard for both the Manufacturer and Distributor Defendants, and recognized that his causation findings are consistent with the MDL and state decisions. *Id.* at 71-72; 72, n. 41.

Finally, Defendants are again incorrect that the claims present "a host of individual issues." *Opp.* at 51. Plaintiffs have alleged a conspiracy that has impacted each class member the same as result of the children having been diagnosed with NAS and their mothers having had opioid prescription histories. These objective, mechanically ascertainable factors build an overwhelming pre-trial indicia of causation into the class definition itself. Instead of serving as grounds to defeat class certification, they allow this Court to distinguish between the unique case at hand versus the cases cited by defendants which contained individualized issues of fact. *See e.g., Sweet v. Pfizer*, 232 F.R.D. 360 (C.D. Cal. 2005) (differences in drug dosage, timing of impacts, and external forces prevent class certification); *Gartin v S&M NuTec, LLC*, 245 F.R.D. 429 (C.D. Cal. 2007) (damage claim involving canine chew treats could not be certified as varying impact on each dog was individual issue). For these reasons, a class should be certified under California law.

E. The Court Can Certify a Class under Ohio Law Ohio Causes of Action

1. Ohio Law Provides for Medical Monitoring Relief

immediate cause" of the injury producing conduct, the plaintiff need demonstrate it was the only cause. *Id.*, at 326. Thus, all Guardians have standing against all defendants because they were immediately injured by the conspiracy. If this Court finds that a class representative that directly used each Defendant product in order to pursue an UCL claim instead of merely victimized by the conspiracy, Plaintiffs request leave to add additional class representatives.

The Sixth Circuit has recognized that class certification is appropriate where the issues of proof and liability are the same due to common elements of law and fact:

In mass tort accidents, the factual and legal issues of a defendant's liability do not differ dramatically from one plaintiff to the next. No matter how individualized the issue of damages may be, these issues may be reserved for individual treatment with the question of liability tried as a class action. Consequently, the mere fact that questions peculiar to each individual member of the class remain after the common questions of the defendant's liability have been resolved does not dictate the conclusion that a class action is impermissible.

Sterling v. Velsicol Chemical Corp., 855 F.2d 1188, 1197 (6th Cir. 1988) (upholding class certification of a class of property owners exposed to toxic chemicals in a landfill).

“[C]ourt-supervised medical monitoring [is] available as an equitable remedy under Ohio law.” *Hirsch v. CSX Transp., Inc.*, 656 F.3d 359, 361 (6th Cir. 2011) (citing *Wilson v. Brush Wellman*, 817 N.E.2d 59, 63-65 (Ohio 2004)); accord *Day v. NLO*, 851 F.Supp. 869, 880 (S.D. Ohio 1994)). As explained by this Court in the underlying matter in *Hirsch v. CSX Transp., Inc.*, No. 1:07-cv-3512, at *18-19 (N.D. Ohio Oct. 22, 2008):

Ohio recognizes medical monitoring as a form of relief. CSXT's view that these eleven Plaintiffs have no injury ignores the theory at the heart of medical monitoring claims. As recognized in the ground-breaking medical monitoring case, *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816, 825, 241 U.S. App. D.C. 83 (D.C. Cir. 1984), an increased risk of disease and accompanying invasion of the interest in avoiding expensive diagnostic examinations is an injury in itself. Stated by a court applying Ohio law [*Day v. NLO*, 851 F.Supp. at 880], which relied heavily on *Friends For All Children*, “[i]t is the combination of traditional tort policy of compensation for reasonable diagnostic procedures and the medical understanding of diseases with protracted latency periods that have led courts to order prospective medical monitoring.”

The *NLO* court approved certification of a class seeking the remedy of medical monitoring:

The focus of the case at bar is the behavior of the Defendants. Fundamentally, all claims rest upon the same alleged misconduct. Therefore, we are confident that the issue of liability is one best litigated by the class as a whole. We are also convinced that should the jury find liability, it will also be appropriate for that jury to render a class wide verdict on the question whether medical evaluation is appropriate for all class members. A finding of liability makes it reasonable for the tort victim to seek a diagnostic evaluation to determine the extent of his or her injuries, if any, and to devise a course of treatment, if required. The

extent and duration of diagnostic monitoring is a matter for medical professionals under the supervision of the court to decide. Viewed in this light, class adjudication of the right to medical monitoring is preferable.

851 F. Supp. at 883-884 (emphasis added). The need for future medical monitoring “is simply a compensable item of damage when liability is established under traditional tort theories of recovery.” *NLO*, 851 F. Supp. at 879-880 (quoting *Potter v. Firestone Tire and Rubber Co.*, 863 P.2d 795, 823 (Cal. 1993)).

2. A Claim for Medical Monitoring Can Be Established by Class-wide Proof

Plaintiffs allege that each Defendant owes a duty to the Legal Guardians, and each Defendant (acting in concert) breached that duty, which resulting in reasonably foreseeable harm of an NAS diagnosis which altered the duty of care owed by the Guardians to the NAS Children. The class definition itself creates are common (and settled) issues of exposure, increased risk, and need for future medical monitoring.

The *NLO* court recognized medical monitoring as an appropriate class wide remedy even though risk varied based on differences in exposure:

Moreover, we are aware of the limits of recovery allowed through the remedy of medical monitoring. The monitoring must be directed toward the disease for which the tort victim is at risk, and will only include procedures which are medically prudent in light of that risk as opposed to measures aimed at general health. *See Potter*, 863 P.2d at 825. ... The type and cost of medical monitoring appropriate in this case will be established by the evidence and determined by the jury under appropriate instructions. If the Plaintiffs can prove that the Defendants exposed them as a class to excessive radiation, then the Plaintiffs’ claims for diagnostic testing and case review by competent medical professionals cannot be contested.

Id. at 881-82 (emphasis added); *see also Hardwick v. 3M Co.*, Case No. 18-CV-1185, 2019 U.S. Dist. LEXIS 169322, at *6-9 (S.D. Ohio Sept. 30, 2019).

3. Under Ohio Law, Medical Monitoring Is Injunctive Relief and Individual Damages Are Irrelevant

Plaintiffs exclusively seek injunctive relief designed to meet the monitoring care duty owed by any Guardians to any NAS Child; thus, it is appropriate for the class as a whole. Defendant's argument that "individualized damages" are at issue is a red herring. The Sixth Circuit rejected this similar argument in *Sutton v. St. Jude Medical SC, Inc.*, 419 F. 3d 568, 572-73 (6th Cir. 2005) and recognized the inherent homogeneity of a monitoring relief, finding that "based on the particular remedy a plaintiff chooses to seek, her burden of proof will vary" and noting that "proving monetary damages is inherently speculative because courts are forced to anticipate the probability of future injury while proving the need for medical monitoring is much less speculative because the issue for the jury is the less conjectural question of whether the plaintiff needs medical surveillance." (Internal citations omitted, emphasis added).

4. Ohio Law of Conspiracy

Under Ohio law, the acts of co-conspirators are attributable to each other, because "[a]ll those who, in pursuance of a common plan or design to commit a tortious act, actively take part in it, or further it by cooperation or request, or who lend aid or encouragement to the wrongdoer, or ratify and adopt the wrongdoer's act done for their benefit, are equally liable." *Williams v. Aetna Fin. Co.*, 700 N.E.2d 859 (1998). Plaintiffs here seek redress for injuries caused by the whole of the conspiracy, not simply the harm caused by each individual conspirator. *See, e.g., Iron Workers Local Union No. 17 Insurance Fund and its Trustees v. Philip Morris Inc.*, 23 F. Supp. 2d 771 (N.D. Ohio 1998) (certifying civil conspiracy claims alleging a common scheme by tobacco companies to shift the increased costs of health care onto others); *Minarik v. Nagy*, 8th Dist. Cuyahoga County No. 26285, 193 N.E.2d 280, 281 (Ohio Ct. App. 1963) ("the conspiracy. . . affects that means and measure of redress; for the party wronged may look beyond the actual participants in committing the injury, and join with them as defendants all who conspired to

accomplish it. . . [and] gives the person injured a remedy against parties not otherwise connected with the wrong.” (emphasis added)). All Defendants are equally liable for damage caused by their conspiracy and Plaintiffs have standing to assert claims against all members of the conspiracy that caused their injury.

Defendants’ causation arguments are also similar to ones raised earlier and rejected by this Court. For example, this Court held:

[T]he record supports an inference that the conduct of each Manufacturer was a substantial factor in producing the harm. *See Pang v. Minch*, 53 Ohio St. 3d 186, 559 N.E.2d 1313, 1324 (Ohio 1990) (where plaintiff suffers a single injury as a result of the tortious acts of multiple defendants, the burden of proof is on the plaintiff to demonstrate that the conduct of each defendant was a substantial factor in producing the harm; thereafter, the burden of persuasion shifts to the defendants to demonstrate that the harm produced by their separate tortious acts is capable of apportionment).

Doc. #: 2561 at 5-6. While Defendants place significant “causation” focus on the role of physicians, this Court recognized that the learned intermediary doctrine only applies if there has been proper warning and instruction to the physician.³¹ The doctrine is inapplicable as a matter of law to cases such as this, “when the very purpose of the Defendants’ alleged scheme was to achieve exactly that result (physician’s act of writing prescriptions).” Doc. # 1025 at 30, 78.

F. The Court Can Certify a Nationwide Class Under RICO

Defendants’ frame their objections to the certification of a nationwide RICO class as attacks on the Named Plaintiffs’ typicality and adequacy. The Named Plaintiffs’ responses are located in Sections II.A and II.C, which address those subjects, respectively.

G. Equitable Considerations Do Not Weigh Against Class Certification

³¹ Doc. # 3058 at 45-46 (“Under this doctrine, so long as a Manufacturer of a prescription drug has properly warned and instructed the physician, i.e. a Learned Intermediary, the Manufacturer “may reasonably assume that the physician will exercise his informed judgment in the patient’s best interests.”) (citing *Tracy v. Merrell Dow Pharm., Inc.*, 569 N.E.2d 875, 878 (Ohio 1991)).

In a last-ditch effort to prevent certification, Defendants contend that equitable considerations weigh against the creation of a (b)(2) class. Their first argument—by now wholly discredited—is that persons “who might otherwise pursue individual relief” may lose their damages claims because opt outs are not allowed. Opp. at 59. Their second argument is that experts disagree about the proper design of a monitoring scheme. This problem, assuming it exists, is a matter to be dealt with at the remedial stage; it is not an objection to class certification. Finally, they argue that the creation of a monitoring program “risks stigmatizing and harming the very children it purports to help.” Opp. at 59-60. The obvious response is that, after the monitoring program is established, guardians who fear stigmatization to an extent that outweighs the benefits of monitoring can keep their wards at home. Although opt outs from (b)(2) classes are not allowed, participation certainly cannot be forced.

The controlling case law on the exact type of medical monitoring and surveillance protocol sought by Plaintiffs recognizes that it is most certainly injunctive and must be evaluated under Rule 23(b)(2).³² Regarding these distinctions, the court in *Donovan v. Philip Morris USA, Inc.*, 268 F.R.D. 1, 25 (D. Mass. 2010) (emphasis added) writes:

Legal damages, while intended to compensate the plaintiff for some harm, may be used for anything. Courts may not put restrictions on monetary awards once paid. Money damages are meant to stand in and compensate in whatever way the plaintiff chooses. Equity, on the other hand, is specific. " **With substitutionary remedies, plaintiff suffers harm and receives a sum of money. Specific remedies seek to avoid this exchange. They aspire to prevent harm, or undo it, rather than let it happen and compensate for it.**" Douglas Laycock, *The Death of the Irreparable Injury Rule*, 103 Harv. L.Rev. 687, 696 (1990). Medical monitoring here is specific [injunctive relief]. Funds not used for this purpose are returned to the defendant.

³² *Yslava v. Hughes Aircraft Co.*, 845 F. Supp. 705, 713 (D.Az. 1993) (“When class certification is sought in the alternative under 23(b)(2) and (b)(3), the 23(b)(2) class is preferred.”). Plaintiffs have alternatively requested certification under 23(b)(3) and the meritorious basis for that relief is set out both in their Motion and interwoven, where appropriate, in their Reply arguments regarding 23(b)(2) treatment as the considerations regarding predominance and cohesion are somewhat overlapping, though predominance is a more stringent requirement.

Plaintiffs are not seeking recovery of money damages so that they can set up their own stand-alone monitoring and surveillance protocol for each NAS Child, pay for it themselves, and then hire and pay for a science panel to supervise the protocol and interpret the results of each case study of “1.” Instead, Plaintiffs seek the creation of a class-wide protocol, enrollment of all the NAS Children in their care in the protocol, the supervision of the Court and the appointed Science Panel over the administration of the protocol,³³ and, finally, the study by the Science Panel of the results derived from the first-in-its-kind longitudinal birth cohort created by the protocol. Complaints, *passim*. The benefit to the Guardians from this purely equitable relief is not money but something far greater: the ability to more properly care for the NAS Children so that their unique risks can be diagnosed, understood, and ameliorated at early stages of development.³⁴

At deposition, Dr. Anand, Plaintiffs’ chief medical expert on the necessary monitoring and surveillance protocol triggered by the NAS diagnosis, explained the need for this injunctive relief:

What it will do is to provide for monitoring surveillance and support that is currently not being provided by the healthcare system or the education system or by the social services system. The kinds of evaluations that we have included in our monitoring [and] surveillance protocol are not done routinely, and it will help diagnose conditions early so that we can address them at a time when they are pliable to being overcome.

³³ Contrary to Defendants’ assertion, Plaintiffs are not seeking court supervision *ad infinitum*. Instead, supervision shall extend in coordination with the Court-appointed Science Panel during the “start-up” phase when the protocol is created and standards for administration are established. Thereafter, supervision can be carried out solely by the Science Panel, if that is the Court’s wish.

³⁴ The late Justice Ruth Bader Ginsberg eloquently discussed the history and nature of equitable relief in American jurisprudence:

Since our earliest cases, we have valued the adaptable character of federal equitable power. See *Seymour v. Freer*, 8 Wall. 202, 218 (1869) (“[A] court of equity ha[s] unquestionable authority to apply its flexible and comprehensive jurisdiction in such manner as might be necessary to the right administration of justice between the parties.”); *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944) (“Flexibility rather than rigidity has distinguished [federal equity jurisdiction].”). We have also recognized that equity must evolve over time, “in order to meet the requirements of every case, and to satisfy the needs of a progressive social condition in which new primary rights and duties are constantly arising and new kinds of wrongs are constantly committed.” *Union Pacific R. Co. v. Chicago, R. I. P. R. Co.*, 163 U.S. 564, 601 (1896) (internal quotation marks omitted); see also 1 Symans, Pomeroy’s Equity Jurisprudence § 67, at 89 (5th ed. 1941) (the “American system of equity is preserved and maintained . . . to render the national jurisprudence as a whole adequate to the social needs . . . [I]t possesses an inherent capacity of expansion, so as to keep abreast of each succeeding generation and age.”).

Grupo Mexicano de Desarrollo, S. A. v. Alliance Bond Fund, Inc., 527 U.S. 308, 336-37 (1999) (Ginsberg, J. dissent).

There is currently a lack of an approach of how we are going to solve this problem. We have these children; and by the way, the opioid crisis is not over, it's still going on even today in 2020. There are thousands, tens of thousands, hundreds of thousands of houses of people being affected by it. And, so, somehow we have to solve this problem. And so this - for this class of individuals, this is one way of solving it.

I also propose in my declaration a scientific panel that reviews the data, that does these kinds of analyses, and changes the approach. ... [E]fforts must be put in the direction to create the longitudinal data that will allow us to make the best decisions for these children and allow them to reach their fullest potential.

Anand Dep. Excerpts at Bilek Declaration, Ex. 2 at 221-222: 8-19 and 1-22.

That the nature of this relief is purely injunctive and evaluated under Rule 23(b)(2) is routinely recognized by courts. *See Gates v. Rohm and Haas Co.*, 265 F.R.D. 208, 230 (E.D. Pa. 2010) (“Plaintiffs’ request for a court-ordered, court-supervised medical monitoring program can be considered a request for injunctive relief.”); *Mehl v. Canadian Pacific Railway Ltd.*, 227 F.R.D. 505, 519 (D.N.D. 2005) (denying medical monitoring class certification under Rule 23(b)(2) because Plaintiffs requested compensatory relief, not “a court-supervised medical monitoring fund or program”); *Wilson*, 817 N.E.2d at 65 (“Court supervision and participation in medical-monitoring cases is a logical and sound basis on which to determine whether the action is injunctive. It has the added advantage of being a bright-line test, which can be readily and consistently applied.”); *Lewallen v. Medtronic USA, Inc.*, 2002 WL 31300899 (N.D. Cal. Aug. 28, 2002) (decision controlled by whether plaintiffs seek “the establishment of a medical monitoring fund, rather than the establishment of a medical monitoring program”); *Gibbs v. E.I. DuPont De Nemours & Co., Inc.*, 876 F.Supp. 475, 481 (W.D.N.Y. 1995) (certifying an exposure-only medical monitoring class under Rule 23(b)(2)). *See also Werlein v. United States*, 746 F. Supp. 887, 895 (D. Minn. 1990) (where “it is necessary to gather and share information regarding

diagnosis and treatment through screening, the Court would consider framing a medical monitoring and information sharing program as injunctive relief”).

In *Day v. NLO, Inc.*, 144 F.R.D. 330, 335-36 (S.D. Ohio 1992), *rev'd on other grounds*, 5 F.3d 154 (6th Cir. 1993), Justice Spiegel offers an especially helpful explanation of how a court can identify medical monitoring claims seeking predominantly injunctive relief:

Relief in the form of medical monitoring may be by a number of means. First, a court may simply order a defendant to pay a plaintiff a certain sum of money. The plaintiff may or may not choose to use that money to have his medical condition monitored. Second, a court may order the defendants to pay the plaintiffs' medical expenses directly so that a plaintiff may be monitored by the physician of his choice. Neither of these forms of relief constitute injunctive relief as required by Rule 23(b)(2).

However, a court may also establish an elaborate medical monitoring program of its own, managed by court-appointed court-supervised trustees, pursuant to which a plaintiff is monitored by particular physicians and the medical data produced is utilized for group studies. In this situation, a defendant, of course, would finance the program as well as being required by the Court to address issues as they develop during the program administration. Under these circumstances, the relief constitutes injunctive relief as required by Rule 23(b)(2).

V. THE REQUIREMENTS FOR CERTIFYING A CLASS UNDER RULE 23(B)(3) ARE MET³⁵

A. Common Issues Predominate

Per this Court in *Gawry*, 640 F. Supp. 2d at 951 (N.D. Ohio 2009), for predominance “a plaintiff must establish that the issues in the suit that are subject to generalized proof predominate over the issues subject only to individualized proof.” Further, “[a] claim will satisfy the predominance requirement for class certification where common evidence exists that proves or

³⁵ A plaintiff may plead “in the alternative.” Rule 8(d)(2) provides that a party “may set out 2 or more statements of a claim or defense alternatively or hypothetically, either in a single count or defense or in separate ones. If a party makes alternative statements, the pleading is sufficient if any one of them is sufficient.” Fed. R. Civ. P. 8(D)(2). To plead in the alternative, a plaintiff “need not use particular words, [but] they must use a formulation from which it can be reasonably inferred that this is what they were doing.” *Gucwa v. Lawley*, 731 Fed. App’x 408, 416 (6th Cir. 2018) (quoting *Holman v. Indiana*, 211 F.3d 399, 407 (7th Cir. 2000)). In the instant cases, Plaintiffs used specific and “particular words” regarding compensatory relief which is clearly requested “in the alternative.” And, indeed, had the NAS Guardians failed to plead alternative relief of the award of compensatory damages and certification under Rule 23(b)(3), the irony is that the Defendants would have found fault with that also and accused them of claim/relief abandonment.

disproves an element on a simultaneous, class-wide basis, thus obviating examination of each class member's individualized position.” *Id.*; see also *Beattie v. Century-Tel, Inc.*, 511 F.3d 564, 566 (6th Cir. 2007) (predominance where common evidence establish liability on a class-wide basis).

The core of the Guardians’ case is the allegation that Defendants’ conspiracy tainted every prescription for opiates that every NAS birth mother received. The conspiracy also connects Defendants to any diversionary opiates that a birth mother might have obtained. When a uniform and pervasive pattern of conduct is alleged, there is predominance even if the common conduct caused varying harm to individual class members.³⁶ *Martin*, 896 F.3d at 408; accord *Tyson Foods, Inc. v. Bouaphakeo*, 136 S.Ct. 1036, 1045 (2016); *In re Hyundai and Kia Fuel Economy Litigation*, 926 F.3d 539, 563 (9th Cir. 2019).

Defendants contend that predominance is lacking because individual issues abound. For example, they argue that the Named Plaintiffs will have to show that every prescribing physician “saw or was exposed to allegedly fraudulent marketing.” Opp. at 49. This is a version of the learned intermediary defense, which the Court has repeatedly rejected. See *In re Nat’l Prescription Opiate Litig.*, 458 F. Supp. 3d 665, 698 (N.D. Ohio 2020), *motion to certify appeal denied*, 2020 WL 3547011 (N.D. Ohio Jun. 30, 2020) (“Given Monroe [County’s] allegations that prescribing physicians were also targets of the misrepresentations, the Court declines to find “the physicians’ act of writing prescriptions breaks the causal chain, as a matter of law, when the very purpose of

³⁶ As explained in the Class Motion, “the Guardians’ pleadings are unique because through their carefully crafted class definition and liability theory they have: (1) established how Defendants’ vast conspiracy to create the secondary, diversionary market for opioids obviates the need for any individual Guardian to establish product identification (or the route of any opioid through the pharmaceutical supply chain) specific to an NAS Child; (2) obviated the need for any dose calculation, because the NAS diagnosis at birth itself is proof of the sufficiency of dosage; (3) excluded other potential sources of exposure, intervening causes, or the relevancy of unique medical histories as the exposure occurred *in utero*; (4) plead a completely uniform actual injury and common medical concern which is based on a credible, non-conjectural risk to the NAS Children which in turn gives rise to immediate and necessary care duties of the NAS Guardians for the benefit of the NAS Children; and (5) established the traceability of Defendants’ bad acts to the Plaintiffs’ harm through the class definition requirement of an opioid prescription for the birth mother. Doc. # 3066, at 39-40.

the Defendants’ alleged scheme was to achieve exactly that result.”). They make similar assertions regarding pharmacies. Opp. at 49-50. But every birth mother can be connected to a pharmacy by means of a filled prescription, and a pharmacy’s participation in the alleged conspiracy—a fact to be decided by a jury on the basis of common evidence—creates a reasonable basis for inferring that every prescription it filled was tainted.

Defendants also seek to fend off class certification by alleging some “appropriate” opioid prescriptions to birth mothers. Opp. at 53. But there is no safe dose of opioids for a gestating fetus, and Defendants took no steps to establish that opioids can safely be taken during pregnancy. Instead, they maximized their profits by improperly influencing the prescribing guidelines. Their failure to depose a single physician shows that this argument is a make-weight. There is no evidence showing that prescriptions to expectant mothers were medically appropriate.³⁷

The predominance requirement is satisfied in the requested nationwide and single-state class actions for the same reason. The evidence relating to the conspiracy, including documents and fact and expert testimony, will be the same for all Guardians. The evidence bearing on the wards’ needs for medical monitoring will be common too.

B. A Class Action is Superior to Other Ways of Proceeding

Class certification is superior when “a class action would achieve economies of time, effort, and expense, and promote . . . uniformity of decision as to persons similarly situated, without sacrificing procedural fairness or bringing about other undesirable results.” *Whiteamire Clinic, P.A., Inc. v. Cartridge World N. Am., LLC*, No. 1:16CV00226, 2019 U.S. Dist. LEXIS 126875 (N.D. Ohio July 30, 2019). Defendants contend that the superiority requirement is not met because

³⁷ It bears mentioning that, because Defendants elected to proceed without filing answers, they have not actually asserted any defenses. Consequently, the Court should ignore any defenses they might conceivably assert as being hypothetical. “[T]he mere mention of a defense is not enough to defeat the predominance requirement [].” *Whiteamire*, 2019 U.S. Dist. LEXIS 126875, at *10-11.

“dozens of potential class members and the children in their care have already brought individual suits.” Opp. at 54. This assertion ignores the fact that aggregation can be advantageous in two situations. “First, and most classically, when many individuals have small damage claims, second . . . when the legal system is flooded by particular types of claims. In these circumstances, aggregation may be efficient because it may avoid duplication and enable faster processing of the multitude of claims.” 2 Newberg on Class Actions § 4:47 (5th ed.). Here, both situations are combined. Although sufficiently many guardians have sued to warrant aggregation, untold numbers of others have not and would benefit from class-based litigation. Finally, any guardian with sufficient interest in controlling the litigation of his or her case can opt out and proceed alone.

Defendants also contend that a class action would be unmanageable and point out that the Named Plaintiffs have not submitted a trial plan. Opp. at 54-55. However, as the preceding discussion of commonality makes clear, the case will be tried on the basis of common evidence showing that the Defendants conspired to maximize the consumption of opioids and that, as a result, every prescription received by a birth mother was tainted, there being no dosage of opioids that has been shown to be safe for a fetus *in utero*.

Finally, Defendants argue that the relief requested, a medical monitoring protocol designed by the Court and informed by a panel of relevant experts, is also unmanageable. Opp. at 56. The Named Plaintiffs entrust this issue to the Court’s discretion. The Court has expressed the desire to help the victims of the opioid crisis and the NAS children are the most innocent members of that enormous group. The Named Plaintiffs are confident that problems relating to the design and implementation of the requested remedy will be overcome.

VI. THE COURT CAN CERTIFY AN ISSUE CLASS

The Named Plaintiffs have moved for certification under Rules 23(b)(2) and 23(b)(3). Recent Sixth Circuit precedent identifies a third option: Certifying a limited issue class under the combination of Rule 23(c)(4) and Rule 23(b)(3). *Martin*, 896 F.3d 405, which the Sixth Circuit revisited in *In re Nat'l Prescription Opiate Litig.*, 976 F.3d 664, 675 (6th Cir. 2020), shows how this can be done.

A. *Martin's Roadmap*

Martin involves claims arising out of groundwater pollution caused by two plumes of chemicals from two different facilities which allegedly caused certain health effects. *Id.* at 409. After finding that the requirements set out in Rule 23(a) were met, the district court certified a limited issues class under Rule 23(c)(4) 23(b)(3). The certification order identified seven issues suitable for class-based litigation whose resolution would advance the litigation materially.

In a carefully reasoned opinion, the Sixth Circuit affirmed the issue class certification. For present purposes, the most important conclusion it reached is that Rule 23(b)'s predominance and superiority requirements apply *only* to the issues on which the Rule 23(c)(4) certification is based. The entire case need not be certifiable under Rule 23(b)(3).

Rule 23(c)(4) contemplates using issue certification to retain a case's class character where common questions predominate within certain issues and where class treatment of those issues is the superior method of resolution. [] A requirement that predominance must first be satisfied for the entire cause of action would undercut the purpose of Rule 23(c)(4) and nullify its intended benefits.

Id. at 413 (internal citation omitted).

In *Martin*, the individual issues preventing certification of the entire case were important, and included actual injury and causation. *Id.* at 414. But certification of the common issues was appropriate even so. Citing *Tyson Foods*, 136 S.Ct. at 1045, the panel wrote that "certification may remain 'proper' even if 'important matters' such as actual injury, causation, and damages will have

to be tried separately.” *Martin*, 896 F.3d at 415. The Sixth Circuit found no inherent incompatibility between issue certification and the defendants’ Seventh Amendment jury trial right either. It cited *Olden v. LaFarge Corp.*, 383 F.3d 495, 509 n.6 (6th Cir. 2004), for the proposition that “if done properly, bifurcation will not raise any constitutional issues.” *Id.* at 417.

B. Applying *Martin* to This Lawsuit

In this case, many issues that are central to the litigation can be resolved once for all class members on the basis of common evidence. The primary example is the existence, *vel non*, of the alleged RICO conspiracy. Other such issues include the potential of exposure to opioids *in utero* to cause harm, the impact of the conspiracy on the availability of information and the frequency with which opioids were prescribed, and Defendants’ knowledge of the dangers associated with the use of opioids by women of childbearing age and expectant mothers.

In sum, if the Court decides that the entire case cannot be certified as a class suit under either Rule 23(b)(2) or Rule 23(b)(3), the Named Plaintiffs urge the Court to certify an issue class limited to questions that can be decided on the basis of common evidence and whose resolution will advance this litigation materially.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was filed electronically on November 13, 2020 with the Clerk of Court and served upon all parties via CM/ECF at the party's registered email address.

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